

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	09/423,943	SAMPATH ET AL.
	Examiner	Art Unit
	Daniel C. Gamett, PhD	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 05/23/2006.
2.  The allowed claim(s) is/are 1,3,6,8-15,17-22,26-28,124 and 125.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 04/24/2006
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 6/16/2006.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Erika Takeuchi on August 3, 2006.

The application has been amended as follows:

In the claims—

1. A method for determining the morphogenic ability of a candidate morphogenic protein ~~or analog thereof~~ to induce new tissue formation at a local defect site at least 6 hours after tissue damage, comprising the steps of:

(a) creating a local defect site accessible to progenitor cells,

(b) administering at least 6 hours after creating the local defect site, said candidate morphogenic protein ~~or analog thereof~~ systemically to said mammal at a site distal from the local defect site, and

(c) measuring the amount of new tissue formation at said defect site,

wherein said local defect site is in renal, skeletal, lung, cardiac, liver, pancreas, uterine, ovarian, gastrointestinal, colon, dermal, osteochondral, chondral, or thyroid tissue, and

wherein said morphogenic protein is selected from the group consisting of: OP1, OP2,

OP3, BMP2, BMP3, BMP4, BMP5, BMP6, BMP9, BMP-10, BMP-11, BMP-12, BMP-15,

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BMP-3b, DPP, Vg1, Vgr-1, 60A protein, GDF-1, GDF-3, GDF-5, GDF-6, GDF-7, GDF-8,

GDF-9, GDF-10, GDF-11, or amino acid sequence variants thereof, or

wherein said candidate morphogenic protein comprises an amino acid sequence having at least 70% homology within the C-terminal 102 to 106 amino acids, including the conserved seven cysteine domain, of human OP1, and

wherein the amount of new tissue formation at said defect site measured in step (c) that is greater than the amount of new tissue formation measured in the absence of administration of said candidate morphogenic protein ~~or analog thereof~~ indicates the activity ability of said candidate morphogenic protein ~~or analog thereof~~ to induce new tissue formation at a local defect site at least 6 hours after tissue damage.

3. A method for determining an optimal dosage of a candidate morphogenic protein ~~or analog thereof~~ for administering to a mammal to induce new tissue formation at a local defect site at least 6 hours after tissue damage, comprising the steps of:

(a) creating a local defect site accessible to progenitor cells,

(b) administering at least 6 hours after creating the local defect site, said candidate morphogenic protein ~~or analog thereof~~ at a dosage to be tested systemically to said mammal at a site distal from the local defect site, and

(c) measuring the amount of new tissue formation at said defect site,

wherein said local defect site is in renal, skeletal, lung, cardiac, liver, pancreas, uterine, ovarian, gastrointestinal, colon, dermal, osteochondral, chondral, or thyroid tissue, and

wherein said morphogenic protein is selected from the group consisting of OP1, OP2,

OP3, BMP2, BMP3, BMP4, BMP5, BMP6, BMP9, BMP-10, BMP-11, BMP-12, BMP-15,

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BMP-3b, DPP, Vg1, Vgr-1, 60A protein, GDF-1, GDF-3, GDF-5, GDF-6, GDF-7, GDF-8,

GDF-9, GDF-10, GDF-11; or

wherein said candidate morphogenic protein comprises an amino acid sequence having at least 70% homology within the C-terminal 102 to 106 amino acids, including the conserved seven cysteine domain, of human OP1, and

wherein the dosage that induces the largest amount of new tissue formation at said defect site measured in step (c) indicates the optimal dosage of said candidate morphogenic protein or analog thereof to induce new tissue formation at a local defect site at least 6 hours after tissue damage.

5. Canceled

7. Canceled

23-25. Canceled

29. Canceled

76. Canceled

125. A method for determining the tissue regeneration activity of a candidate morphogenic protein or analog thereof at least 6 hours after tissue damage, comprising the steps of:

(a) creating a local defect site accessible to progenitor cells,

(b) administering at least 6 hours after creating the local defect site, said candidate morphogenic protein or analog thereof systemically to said mammal at a site distal from the local defect site, and

(c) measuring the extent of replacement tissue regeneration at the local defect site, induced by the administration of said candidate morphogenic protein ~~or analog thereof~~, wherein said local defect site is in renal, skeletal, lung, cardiac, liver, pancreas, uterine, ovarian, gastrointestinal, colon, dermal, osteochondral, chondral, or thyroid tissue, and wherein said morphogenic protein is selected from the group consisting of: OP1, OP2, OP3, BMP2, BMP3, BMP4, BMP5, BMP6, BMP9, BMP-10, BMP-11, BMP-12, BMP-15, BMP-3b, DPP, Vg1, Vgr-1, 60A protein, GDF-1, GDF-3, GDF-5, GDF-6, GDF-7, GDF-8, GDF-9, GDF-10, GDF-11, or amino acid sequence variants thereof; or wherein said candidate morphogenic protein comprises an amino acid sequence having at least 70% homology within the C-terminal 102 to 106 amino acids, including the conserved seven cysteine domain, of human OP1, and wherein the amount of tissue regeneration at said defect site measured in step (c) that is greater than the amount measured in the absence of administration of said candidate morphogenic protein ~~or analog thereof~~ indicates the tissue regeneration activity of a candidate morphogenic protein ~~or analog thereof~~ at least 6 hours after tissue damage.

*Drawings*

2. The drawings filed on 05/23/2006 are acceptable subject to correction of the following informalities. The panels of Figure 1 and Figure 2 are not labeled A-C and therefore are not in congruence with the Brief Description of the Drawings in the specification. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG  
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3 August 2006

*David Romeo*  
DAVID S. ROMEO  
PRIMARY EXAMINER